

Remarks/Arguments

Claims 1, 2, 6, 7, 10, 13 are currently pending in the instant application. Claims 6 and 7 have been amended.

IDS

The Examiner has objected to the IDS filed on February 17, 2009; specifically the Examiner alleges that Beers and Berkow, Zamnowski, and Borowicz have not been supplied and that Mutschler was not provided with an English translation. Applicant has reviewed the IDS filed on February 17, 2009 and has found that the Examiner is correct with respect to the Zamnowski, Borowicz, and Mutschler references. However, Applicant respectfully disagrees with respect to the Beers & Berkow reference. Attached, as Appendix A is the Electronic Filing Receipt. The Beers/Berkow reference is the "Merckmanual.pdf" file. For the convenience of the Examiner, Applicant has attached a copy of this reference. Applicant also, concurrently herewith, submits a revised IDS correcting the deficiencies of the IDS of February 17, 2009. Applicant notes that it does not possess an English translation of the Mutschler reference or an English abstract.

35 U.S.C. §112

The Examiner has rejected claims 6 and 7 as being dependent upon canceled claim 5. Applicant has amended claims 6 and 7 to properly depend from claim 1. As this rejection is now moot, Applicant requests its withdrawal.

35 U.S.C. §103(a)

The Examiner reiterates her previous argument that Czuczwar and Levy teach that carbamazepine is an effective anti-epileptic medicament and that carbamazepine can be administered along with an additional anti-epileptic medication. She further alleges that Suter teaches AMP397 is a known AMPA receptor antagonist and an anti-convulsive. The Examiner then alleges that it would be obvious to combine the carbamazepine of Czuczwar and Levy with the AMP397 of Suter. The Examiner further references Decker as teaching that when adding a second anti-epileptic to a treatment regime, it is advantageous to choose a drug with a different mechanism of action from the first.

In Applicant's first response Applicant identified the results disclosed in Table I. (page 5 of the published application). These results demonstrate that alone, AMP397 provided no protection. However, when combined with carbamazepine the combination drastically improves protection against seizures over either active used alone. As AMP397 provides no protection when used as a sole treatment, the combination treatment exhibits synergistic protection against

seizures. This is not taught or suggested by the prior art and is an unexpected result. While Decker suggests considering a dual drug treatment regimen, it fails to even mention the possibility of synergistic results stemming from such a combination treatment. More specifically it fails to suggest that synergistic results would be expected from Applicant's claimed combination. Additionally, the example from Czuczwar cited by the Examiner likewise fails to suggest that one of skill in the art would expect to achieve a synergistic result with the claimed combination. The Examiner asserts that Figure 1 of Czuczwar demonstrates that while 2mg/kg of LY300164 alone offers no protection from seizures, its combination with carbamazepine lowers the ED₅₀. However, Czuczwar does not demonstrate that a combination of carbamazepine and LY300164 actually increases the amount of patients protected against seizures. A reduction in ED₅₀ only demonstrates a reduced amount of carbamazepine to achieve the same result as previously achieved at a higher dose. This does not demonstrate the benefit of Applicant's claimed combination which actually increases the number of mice protected against seizures at a given dosage of carbamazepine when also treated with AMP397. As the Examiner has provided no evidence establishing a relationship between a reduction in ED₅₀ and an increase in number of patients treated, Applicants respectfully submit that the claimed invention demonstrates unexpected results.

Moreover, the findings of Czuczwar are irrelevant to those of the claimed invention. The



structures of LY300164,

, from the Czuczwar reference differs



completely from that of the claimed AMP397,

. Thus, even if,

arguendo, Czuczwar taught that a combination of carbamazepine and LY300164 did increase the number of animals protected, one of ordinary skill in the art would not expect this same result from AMP397 which differs so drastically in structure. Accordingly, Applicant's results would still be unexpected.

Lastly, Examiner has objected to the fact that the specification does not specifically state that the results demonstrated in Table 1 were unexpected. There is no requirement under USPTO rules or case law that Applicant "claim [in the specification] that the results disclosed in Table 1 are unexpected." Indeed, as the prior art fails to suggest such a result, and as the Examiner has provided no evidence that would rebut the unexpectedness of these findings, Applicant respectfully submits that, based upon the evidence of record, Applicant has

demonstrated that claimed combination exhibits unexpected results and thus is not obvious over the cited art. Applicant thus requests withdrawal of the obviousness rejection.

Respectfully submitted,



Daniel Woods
Attorney for Applicant
Reg. No. 59,864

Novartis Pharmaceuticals Corporation
One Health Plaza, Bldg. 101
East Hanover, NJ 07936
(862) 778-9587

Date: 10/14/09